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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,034	09/22/2003	James D. Ralph	SPINE 3.0-441 CONT CONT	1511
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LERNER, DAVID, et al.				
600 SOUTH AVENUE WEST				
WESTFIELD, NJ 07090				
EXAMINER				
NELSON, CHRISTINE L.				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
07/19/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/667,034

**Applicant(s)**

RALPH ET AL.

**Examiner**

CHRISTINE NELSON

**Art Unit**

3775

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, 21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, 21, and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 31, 2011 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, 21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. (US 6,592,624) in view of Hamada (US Patent 6,425,920).

Regarding Claims 1, 4, 9, and 19, Fraser et al. discloses an intervertebral spacer (Figure 1) that is porous (Column 5, lines 55-56) with a beveled edge (see Figures 1 and 2), an upper portion including an upper surface (Figure 2, 42) and a lower portion including a lower surface (Figure 2, 46) where the upper and lower surfaces are

displaced from each other a maximum distance along a first axis. Fraser further discloses a central trunk separating the upper and lower portions (16) where an upper relative angle designation mark (Figure 4, 20) is formed on the upper portion and a lower relative angle designation mark (Figure 4, 21) is formed on the lower portion, the upper and lower relative angle designation marks being separated by the central trunk and formed along the first axis so that the upper and lower relative angle designation marks are visible when the spacer is attached to an insertion tool. Please note: it appears that the relative angle designation marks would still be visible with a tool engaged; however, the tool is not positively recited, so it would depend upon the tool being used. Fraser et al. does not show or specify a specific tool for insertion, and the implant may be inserted in multiple directions (Column 7, lines 3-6). Fraser teaches an upper radial flange (Figure 4, 54) disposed between the upper surface and the annular groove, and a lower radial flange (56) disposed between the lower surface and the annular groove.

Fraser fails to disclose a central bore formed through the upper and lower surfaces, at least one of the upper and lower surfaces having a center that is substantially flat, the central bore formed through at least a portion of the center. However, Hamada teaches a spacer body central bore (707) passing through the upper (703) and lower (705) surfaces where both of the surfaces are substantially flat, and the upper and lower surfaces diametrically tapered (as seen in Figure 60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the invention of Fraser with the central bore as taught by Hamada in order to

provide an area for osteogenic materials to be placed to provide for improved ingrowth and stability of the implant once placed.

Regarding Claims 2, 7, and 10, Fraser discloses the upper and lower surfaces of the spacer body diametrically tapered (Figure 7).

Regarding Claims 6 and 13, Fraser discloses the annular groove as tapered (Figure 6).

Regarding Claims 18 and 21, Fraser discloses the relative angle designation marks extending from a wall of the annular groove to either the upper or lower surface (Figure 6).

Regarding Claims 24-26, Fraser discloses that the upper and lower relative angle designation marks are grooves (Figures 5 and 6).

### ***Response to Arguments***

Applicant's arguments with respect to Claims 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, 21, and 24-26 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE L. NELSON whose telephone number is (571)270-5368. The examiner can normally be reached on Monday through Friday 8:30-5:00, first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, SPE, at (571) 272-4746.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700\_Workgroup\_D\_Inquiries@uspto.gov.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINE L. NELSON/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775